

Delegate Workshop

Metrological Traceability

Introductory Comments – W. E. May

Implementation of Standardization and Traceability in Laboratory Medicine
– M. M. Müller

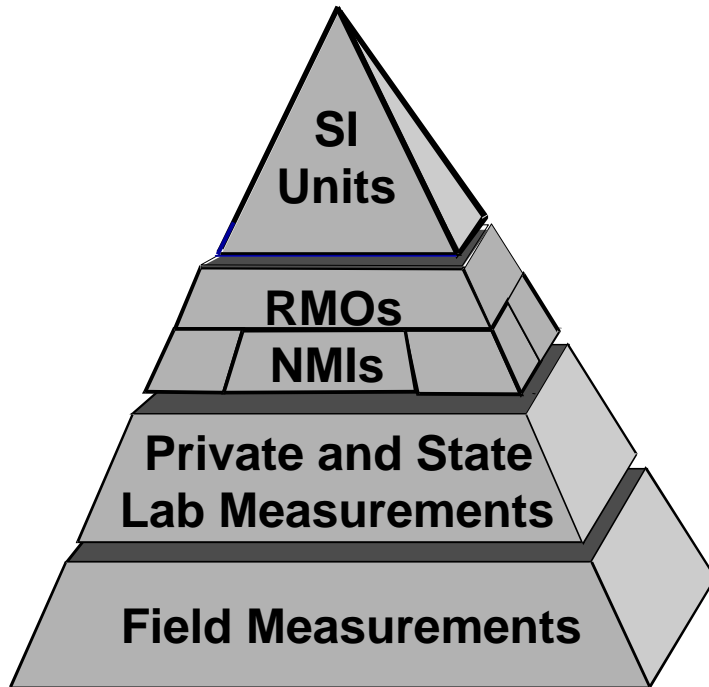
Implementing Metrological Traceability in Laboratory Medicine: JCTLM Role
– W. E. May

Implementing Metrological Traceability in Laboratory Medicine: NCCLS Role
– M. L. Salit

Metrological Traceability in Laboratory Medicine: A Manufacturer's Perspective
– R. R. Miller, Jr.



Traceability: The property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties.
(VIM)



Uncertainty (of measurement): “A parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.”

Drivers for Improved Quality in Clinical Measurements

- U.S. HC Measurement Costs
 - U.S. Spends ~ \$1.1 trillion on Health Care
 - ~10-15% associated with measurement
 - Non-diagnostic measurements cost ~\$40B
- German Health report 1998
 - Costs of repeat measurements amounts to **1.5 B US\$** per year in Germany
- Medical Decision-Making
 - Incorrect diagnosis and treatment
 - Impairment of patient well-being



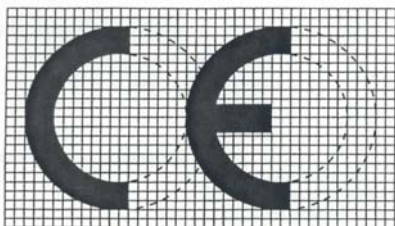
New Regulatory Requirement: EU IVD Directive



A New Driver:

EU IVD Directive to go into effect 2003

- Worldwide *in vitro* diagnostic device market is ~\$20B;
- **>60% of European market is supplied by U.S.**



Stated Purpose of Directive

- Eliminate trade barriers *within Europe* by ensuring access to the entire EU market with one single product approval (CE Mark)

Major Requirement

- IVD Calibrators and/or control materials must be traceable to ***“standards of a higher order”***
 - nationally/internationally recognized *reference methods and/or certified reference materials*

Scheduled Implementation

- First IVD product with CE Mark may be placed from June 2000 onwards
- All *new* IVD products *must* have mark by December 2003 (may be delayed)
- Existing IVD products may be sold without the CE mark until December 2005

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